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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/644,469	08/20/2003	Richard A. Shimkets	Cura-904	6214

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EXAMINER	
MYERS, CARLA J	

ART UNIT	PAPER NUMBER
1634	

DATE MAILED: 02/13/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/644,469	SHIMKETS ET AL.	
	Examiner	Art Unit	
	Carla Myers	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-25 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-25 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Election/Restrictions

1. Prior to setting forth the restriction requirement, it is pointed out that Applicants have presented claims 15-16 and 25 in improper Markush format. See Ex parte Markush, 1925 C.D. 126 and In re Weber, 198 USPQ 334. Claims 15 and 16 are improperly joined as the claimed methods require the use of distinct compounds – i.e., a compound which decreases FGF7 mRNA levels, a compound which decreases protein levels and a compounds that inhibits FGF7 activity. A reference against methods using one of the compound would not be a reference against the methods using the other types of compounds. Similarly, claim 25 requires the use of distinct agents for treatment purposes – i.e., agents which comprise FGF7 protein and agents which increase FGF7 protein levels. Again, a reference against treatment methods using FGF7 protein would not be a reference against the treatment methods using compounds that increase FGF7 protein levels. Therefore, the restriction will be set forth for each of the various groups, irrespective of the improper format of the claims, because the claims do not recite proper species. Upon election, Applicants are required to amend the claims to set forth only the elected inventive groups.

2. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-5, drawn to methods to detect a mutation in a FGF7 nucleic acid, classified in Class 435, subclass 6.

II. Claims 6-8, drawn to methods to detect a mutation in a FGF7 protein, classified in Class 435, subclass 7.1.

III. Claims 9-14, drawn to methods to diagnose hypophosphatemic condition using an agent to detect a change in the level of FGF7 protein, classified in Class 435, subclass 7.2.

IV. Claims 15-16, drawn to methods of treatment of a hypophosphatemic condition using an agent that decreases FGF7 mRNA levels, classified in Class 514, subclass 44.

V. Claims 15-16, drawn to methods of treatment of a hypophosphatemic condition using an agent that decreases FGF7 protein levels, classified in Class 514, subclass 1, further classification cannot be determined without additional information regarding the structure of the agent.

VI. Claims 15-16, drawn to methods of treatment of a hypophosphatemic condition using an agent that inhibits FGF7 protein activity, classified in Class 424, subclass 130.1, further classification cannot be determined without additional information regarding the structure of the agent.

VII. Claims 17-18, drawn to methods of treatment of a hyperphosphatemic condition using a nucleic acid encoding a FGF7 protein, classified in Class 514, subclass 44.

VIII. Claims 19-20 and 25, drawn to methods of treatment of a hyperphosphatemic condition using a FGF7 protein, classified in Class 514, subclass 12.

IX. Claims 21-22 and 25, drawn to methods of treatment of a hyperphosphatemic condition using an agent that increases FGF7 protein levels, classified in Class 514, subclass 1, further classification cannot be determined without additional information regarding the structure of the agent.

X. Claims 23 and 24, drawn to methods of treatment of a hyperphosphatemic condition using a population of cells, classified in Class 424, subclass 93.1.

3. The inventions are distinct, each from the other because of the following reasons:

Inventions I-X are drawn to patentably distinct methods, having different objectives, requiring the use of different reagents and having different process steps. The methods of invention I require the use nucleic acid probes or primers, involve performing nucleic acid sequencing, hybridization or amplification steps and accomplish the objective of detecting a mutation in a nucleic acid in order to diagnose a hypophosphatemic condition. The methods of invention II require the use antibodies or other reagents that specifically detect mutations in a protein, involve performing protein ligand binding assays or protein sequencing assays in order to accomplish the objective of detecting a mutation in a protein in order to diagnose a hypophosphatemic condition. The methods of invention III require the use of antibodies and other reagents that detect wildtype FGF7 protein, involve performing protein detection assays and accomplish the objective of detecting a change in the level of FGF7 protein in order to diagnose a hypophosphatemic condition. The methods of invention IV involve using an agent that decreases mRNA levels and treating a patient with said agent in order to accomplish the objective of treating a hypophosphatemic condition. The methods of invention V involve using an agent that decreases protein levels and treating a patient with said agent in order to accomplish the objective of treating a hypophosphatemic condition. The methods of invention VI involve using an agent that decreases FGF7 activity and treating a patient with said agent in order to accomplish the objective of treating a

hypophosphatemic condition. The methods of invention VII involve using a nucleic acid that encodes FGF7 and treating a patient with said nucleic acid in order to accomplish the objective of treating a hyperphosphatemic condition. The methods of invention VIII involve using a FGF7 protein and treating a patient with said protein in order to accomplish the objective of treating a hyperphosphatemic condition. The methods of invention IX involve using an agent that increases FGF7 activity and treating a patient with said agent in order to accomplish the objective of treating a hyperphosphatemic condition. The methods of invention X involve using a population of cells and treating a patient with said population of cells in order to accomplish the objective of treating a hyperphosphatemic condition. Accordingly, the methods of inventions I-X each have a different objective and effect and are patentably distinct over one another.

4. These inventions are distinct for the reasons given above and have acquired a different status in the art as demonstrated by their divergent subject matter. Further, these inventions require different database searches that are not co-extensive. For example, a search for methods for diagnosing a hypophosphatemic condition by detecting a mutation in a FGF7 nucleic acid would not be co-extensive with a search for methods of treating a hypophosphatemic condition using an agent that inhibits expression of FGF7 nucleic acids. Further, a reference which anticipates or renders obvious methods for diagnosing a hypophosphatemic condition by detecting a mutation in a FGF7 nucleic acid would not also necessarily anticipate or render obvious methods of treating a hypophosphatemic condition using an agent that inhibits expression of FGF7 nucleic acids. Similarly a finding that obvious methods for diagnosing a

hypophosphatemic condition by detecting a mutation in a FGF7 nucleic acid is novel and unobvious over the prior art would not necessarily extend to a holding that methods of treating a hypophosphatemic condition using an agent that inhibits expression of FGF7 nucleic acids. is also novel and unobvious over the prior art. Accordingly, examination of these distinct inventions would pose a serious burden on the examiner and therefore restriction for examination purposes as indicated is proper.

5 . Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

6. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carla Myers whose telephone number is (571) 272-0747. The examiner can normally be reached on Monday-Thursday from 6:30 AM-5:00 PM. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones, can be reached on (571)-272-0745.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance.

Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Carla Myers

January 30, 2006

CARLA J. MYERS
PRIMARY EXAMINER